



**HEALTH PRODUCTS AND FOOD
BRANCH**

PUBLIC ADVISORY COMMITTEE

ANNUAL REPORT

January 2004

Public Advisory Committee Members

Wayne Busch, Chair
Prairie Sector

Dominic Bergeron, Co Chair
Ontario

Prairies Sector

Reverend Robert Girard.
Lena Hozaima
Robert Grose

Atlantic Sector

Don Holloway
Thomas Connor
Daniel Lazaric

Western Sector

Sandra Wood
Yoe Sook Youn
Adam Andruschak

Québec Sector

Claudine Larocque
Jocelyn Côté
Neil Faulkner

Ontario

Nadine Blum
Nancy McColl

LETTER FROM THE CHAIR

On behalf of the Public Advisory Committee (PAC), it is my pleasure to present to you, Ms. Diane Gorman, Assistant Deputy Minister of the Health Products and Food Branch, the first HPFB Public Advisory Committee report.

The purpose of this annual report is to provide an overview of the accomplishments over the past year and to identify the Committee's plans and priorities for 2004.

I am pleased with the Committee's significant contributions and progress since its launch in November 2002. I look forward to the upcoming opportunities you and your Branch Executive Committee will seek from the Committee for future branch issues and initiatives.

On behalf of the Public Advisory Committee, I would also like to extend my sincere appreciation and thanks to the PAC secretariat and the Office of Consumer and Public Involvement for all of their support throughout the year.

As we begin another year, I would like to wish you a happy and healthy 2004.

Sincerely,

Wayne Busch
Chair, Health Products and Food Branch Public Advisory Committee

I. Introduction

Launched in November 2002, the Public Advisory Committee (PAC) is a forum that provides advice from the consumer's perspective on issues and initiatives as requested by the Health Products and Food Branch (HPFB) of Health Canada. The Committee is a component of the Branch's strategy to increase transparency and public involvement through consultation.

The PAC's mandate is threefold: to provide the Assistant Deputy Minister and the Branch Executive Committee with advice from a public perspective on Branch issues and initiatives; to provide guidance to the Office of Consumer and Public Involvement (OCAPI) and the HPFB related to planning and management public-involvement activities; and to advise on increasing the effectiveness of OCAPI and HPFB communications to the consumer/public.

The PAC is presently composed of 16 members of the public from across Canada, including men and women of various ages, education, cultures and language backgrounds.

Although launched late in 2002, the Committee was still able to conduct four meetings before the end of the calendar year. This first annual report provides a record of the PAC's achievements during that brief period, as well as insight into the Committee's future direction and goals.

II. Key Activities: Striving for Excellence in Public Involvement

The PAC's first meeting was held in November 2002 and consisted primarily of information sessions that explained the Branch's roles and responsibilities. Committee members received overviews of the HPFB and OCAPI, as well as presentations on citizen engagement and the government's Speech from the Throne.

Subsequent information sessions introduced the regulatory process, decision-making framework, drug-approval process, and patented medicines. A presentation on the new *Nutritional Labelling Regulations* provided the Committee with an example of a current initiative. Special sessions included a tour of the Biologic and Genetic Therapies Directorate laboratory, as well as an introduction to Western Region operations during the meeting in Vancouver.

III. Key Achievements: Highlights of Advice Provided by the PAC

Health Products and Food Branch Issues and Initiatives

a) Canada's Food Guide

Asked to advise on HPFB's review of *Canada's Food Guide*, the PAC suggested that the Branch address the needs of vegans and vegetarians—particularly among younger Canadians—and clarify the guide's definition of the word “portion.” In addition, the PAC felt that Health Canada should promote the guide by developing advertising partnerships with industry.

b) Openness and Transparency

Presentations to the PAC introduced the topics of openness and transparency, as well as the Therapeutic Access Strategy. The PAC was asked to provide advice on basic principles and concepts that should be considered in comprehensive HPFB definitions of transparency and openness.

From the Committee's perspective, the term openness derives from honesty and clarity—from a commitment to serve Canadians equitably, and to proactively inform and engage all Canadians in timely and relevant ways. Transparency requires adherence to principles of accountability and full disclosure. Successful achievement of openness and transparency will be indicated by the trust that is established between the Branch and Canadians.

c) HPFB Integrated Planning

Members received copies of the HPFB business plan as well as a presentation on HPFB's integrated approach to planning. Asked to provide advice on key issues and trends in the external environment, the Committee identified the need to shift from a traditional health-delivery model to a wellness approach that focuses on disease prevention and health promotion. The PAC also recommended that the Branch seize opportunities for international harmonization of standards and greater regulatory cooperation. Furthermore, the Committee recognized that advances in science and technology will offer new benefits and options to Canadians, but that there are related and significant moral, ethical and privacy issues that should be addressed through public dialogue. Finally, the PAC stated that the public expects to have input into decision-making, and that Canadians are increasingly more able and willing to be involved.

Concerning HPFB strategic directions, the PAC suggested that Health Canada strive for greater transparency by enabling Canadians to gain greater knowledge about regulatory processes, specifically in the area of drug review. The Committee also advised that Branch strategic direction should focus on disease prevention, rather than cure.

IV. Planning and Management of Public Involvement Activities

a) Food Irradiation

PAC members were asked by the Food Directorate to provide advice on issues related to food irradiation and the consultations that took place. The Committee noted that Health Canada appears to promote rather than explain food irradiation. Furthermore, the PAC recommended the department should clearly indicate industry's interest in food irradiation especially in relation to the health of Canadians. The Public Advisory Committee also felt that Health Canada should inform consumers that food irradiation neither compensates for the mishandling of food, nor reduces the danger of serving undercooked food.

b) Regional Networks of Citizens

PAC members provided advice on the creation of regional citizen forums. The Committee supported the creation of such forums, but suggested that they be called regional citizen networks (RCNs). PAC members agreed it should not be involved in selecting individual RCN members, but wanted the option to participate in developing the regional networks.

c) Health Protection and Legislative Renewal

The recent Speech from the Throne committed Health Canada to undertake a second round of consultations on a proposal for a new Health Protection Act. In advance of these consultations, the department asked the PAC members for feedback on planned general-public sessions (GPSs). Committee members raised particular points of concern:

- The 75-minute GPS presentation should be shortened to allow more time for discussion.
- Presentation slides lacked visual impact.
- Values and principles should be addressed before moving into specific themes.
- Participant worksheets should contain the same questions as the clause-by-clause proposal.
- Small discussion groups worked well, particularly when they included Health Canada staff members, who acted as facilitators within each group.

Following a presentation on the new proposed Health Protection Act, Committee members chose to examine three elements in detail: i) general safety requirements, ii) advertising, and iii) communicable diseases.

The PAC members were in favour of proposed changes to the general safety requirements, as well as the idea of a safety net in absence of regulations. Committee members expressed concerns about direct-to-consumer advertising of prescription drugs, but recognized the benefit of this practice insofar as it delivers information to the public. However, there was strong opposition to the proposed appointment of quarantine officers in the Act's section on communicable diseases; PAC members felt these officers would wield power that was not commensurate with their medical expertise.

V. Information Dissemination to the Public

a) Biotechnology and Human Health

The PAC was consulted on the Biotechnology and Human Health communications plan. Though PAC members were generally supportive of the plan, they questioned whether a website should be the sole communications vehicle and recommended that the Branch consider complementary tools, such as print materials and education kits. The Committee also suggested that the website would have to be promoted through advertising even to attract involved and informed Canadians, and that special efforts would be required to reach the broader public.

Throughout discussions, the Committee expressed concern that the communications plan was at times confused in its promotion of both biotechnology and Health Canada's role in the area. PAC commended the Office of Biotechnology and Science for providing balanced information, and stressed the need for broad education about the science, rather than detailed information about the regulatory process.

b) Risk Communication

Committee members were asked to provide a public perspective—and advice—on risk-communication issues concerning three major challenges (Acylamide, West Nile Virus and SARS) faced by the Health Products and Food Branch. The PAC grouped its recommendations according to three themes, and offered guidance on risk communication related specifically to Bovine Spongiform Encephalopathy (BSE).

i) Theme One: Respond early and quickly

- Be proactive and commence communication as soon as possible, even if the science is unclear. (Consistent with senior management priority)
- Recognize when issues might be perceived as dangerous or threatening.
- Consult the public.
- Consider the experience of other jurisdictions.

ii) Theme Two: Message content

- Respect the public's perspective and acknowledge when there is perceived danger, even if science is unclear. (Consistent with senior management priority)
- Report on actions taken and planned.
- Indicate what people can do to protect themselves.
- Explain potential risks in simple terms.

iii) Theme Three: Communication mechanisms

- Respond through multi- and cross-media platforms.
- Deploy spokespersons that can deliver clear and concise sound bites.
- Use community-based organizations.
- Develop standard risk-communication tools and templates and experiment more freely with these items. (Consistent with senior management priority)

BSE

The case of an Alberta cow infected with BSE arose four days before a PAC meeting in the fall of 2002. Asked for advice on communicating the risks associated with this issue, Committee members observed that:

- Health Canada must show leadership, present a unified front and provide the public with clear and accurate scientific reporting, as well as regular information updates.
- Canadians look to the Health Minister to provide truth about BSE with respect to human-health issues, and to reassure Canadians that the government is responding accordingly.
- Canadians expects Health Canada to report on what it knows, and how it plans to act.

2003 HPFB PAC Annual Report

- Canadians want to know what is being done with the remains of infected animals. The public is not convinced that rendering (the sterilization process used to prepare animal carcasses for industrial use) is safe, and is concerned about the impact on the safety of human foods.

c) Communicating Drug Safety Information

The Committee was asked to help prioritize previously identified strategies for communicating drug-safety information, and to suggest ways HPFB might work with other healthcare stakeholders to implement a shared-responsibility model. According to this model, all parties involved in the communication of new health-product safety information work together to ensure that relevant, easily accessible and understandable information reaches its intended audience in a timely fashion.

Among other recommendations, Committee members suggested that HPFB:

- Ensure that it is effectively branded so that Canadians recognize the link between the Branch and drug-safety information.
- Involve healthcare providers to help ensure effective dissemination, visibility and use of drug-safety information.
- Implement mandatory requirements for healthcare professionals to report adverse drug reactions.
- Encourage healthcare professionals to help consumers—especially those most at risk—gain access to information; for example, practitioners could distribute drug-fact sheets with each prescription.
- Produce educational kits and posters to encourage consumers to seek out information.
- Ensure adverse drug-reaction reporting is addressed in medical-school curriculums.
- Partner with stakeholders to provide public-information clinics.
- Increase support for shared responsibility by building awareness of the model among various stakeholders.
- Respect the role consumers should play in the shared-responsibility model.

VI. Evaluation and Feedback: Continuous Improvement and Lessons Learned

Committee members appreciate receiving background information two weeks prior to each meeting, and believe the opportunity to prepare contributed to the significant progress PAC was able to achieve during its first few months of existence. Members are also eager to ensure that each consultation session includes ample time for deliberation—a goal that is facilitated through clear Branch objectives and well-defined expectations.

VII. The Road Ahead: Plans and Priorities for 2004

The Public Advisory Committee will continue to align itself with the priorities of the Health Products and Food Branch. PAC wishes to focus on strategic Branch issues; however, the Committee recognizes the need to address program-specific issues, as well.

The PAC recognizes that some of the challenges ahead include bringing new members on to the committee, maintaining the interest of those on the committee as well as continuing to facilitate communication between members.

The Committee acknowledges the efforts made by OCAPI to provide the PAC with feedback on how the advice they provided was used in the decision-making process. The feedback report provided by the Director General of OCAPI at each meeting is useful, however members would appreciate more direct feedback from the programs that consulted with them.

The Public Advisory Committee members also greatly appreciate how the next upcoming meetings will be organized around themes and greatly look forward to receiving information on forward agenda items.

Annex One

Upcoming Meetings

Winter

February 20-21st, 2004

Ottawa, Ontario

Theme: Openness and Transparency

- Openness and Transparency
- Public Involvement Strategy
- Legislative Renewal: Advertising of Health Products
- Dispute Resolution

Spring

May 28-29th, 2004

Quebec City, Quebec

Theme: Enabling Innovation for Better Health Outcomes

- Animal Biotechnology in Food Use
- Health Canada's Framework on Biotechnology
- Antimicrobial Resistance

Fall

October 1-2nd, 2004

Ottawa, Ontario

Annex Two

Meetings Held in 2002-2003

Fall 2002

November 22-23rd, 2002 **Ottawa, Ontario**

- Overview of the Health Products and Food Branch (information)
- Overview of the Office of Consumer and Public Involvement (information)
- Citizen Engagement (information)
- Speech From the Throne and HPFB Initiatives (information)
- Food Irradiation

Winter 2003

January 31-February 1st, 2003 **Ottawa, Ontario**

- Regulatory Process (information)
- Decision- Making Framework (information)
- Drug Approval Process (information)
- Nutritional Labelling (information)
- Review of Canada's Food Guide
- Regional Network of Citizens

Spring 2003

May 22-23rd, 2003 **Vancouver, British Columbia**

- Western Regional Office (information)
- Legislative Renewal
- Risk Communication
- Biotechnology and Health Communication Plan

Fall 2003

October 17-18, 2003 **Ottawa, Ontario**

- Patented Medicines (information)
- Openness and Transparency (part one)
- Communicating Drug Safety Information
- Health Products and Food Branch Integrated Planning